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Federal Document Clearing House Congressional Testimony

December 11, 2001, Tuesday

SECTION: CAPITOL HILL HEARING TESTIMONY

LENGTH: 7968 words

COMMITTEE: HOUSE APPROPRIATIONS

HEADLINE: DANGERS OF OXYCONTIN

BILL-NO: H.R. 2156 \_\_\_\_\_ Retrieve Bill Tracking Report  
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TESTIMONY-BY: DR. PAUL D. GOLDENHEIM, ON BEHALF OF

AFFILIATION: PURDUE PHARMA L.P.

BODY:

STATEMENT OF DR. PAUL D. GOLDENHEIM ON BEHALF OF PURDUE PHARMA L.P.

BEFORE THE SUBCOMMITTEE ON COMMERCE, JUSTICE, STATE, THE JUDICIARY,  
AND RELATED AGENCIES OF THE HOUSE COMMITTEE ON APPROPRIATIONS

DECEMBER 11, 2001

MR. CHAIRMAN:

On behalf of Purdue Pharma L.P., the distributor of OxyContin taking the time to hold this hearing. We at Purdue are more distressed than anyone that OxyContinC, which is providing so much relief to so many people, is being abused, and we deeply regret the tragic consequences that have resulted from the misuse of this medicine.

The availability of OxyContin is critical for countless patients who are suffering from moderate to severe pain where a continuous around-the-clock analgesic is needed for an extended period of time. Unfortunately for those patients, concern generated by the abuse of OxyContin has mushroomed to the point of hysteria in some locations, with the result that some patients are asking their doctors to switch them to less effective drugs, some doctors are refusing to renew patients' prescriptions for OxyContin and some pharmacies are no longer willing to carry OxyContin for their patients. Purdue receives alarming reports every day from physicians and patients.

At the same time, naive teenagers out for a thrill, and others, are misusing and abusing OxyContin' and other prescription drugs. For some, the consequences are tragic. They do not understand that the

#### 10. What is the Solution?

Perhaps the single most important tool to prevent abuse is education. A survey released last week by the National Association of State Controlled Substances Authorities (NASCA) reveals that NASCA members believe that diversion education and pain management education for prescribers are more effective than any other means of combating prescription drug abuse. To that we would add - as our own commitment to educational initiatives demonstrates - education of youngsters, community leaders, non-prescriber health care professionals and law enforcement personnel.

Education of healthcare professionals about the issues of prescription drug abuse is critical. Purdue has assumed a leadership role. Educating teenagers about the risks and dangers of prescription drug abuse is critical, and we have initiated an important program. Better information is critical, and we have initiated efforts to develop more reliable and timely information.

Prescription Monitoring Programs ("PMPs") would help. The PMPs in Kentucky and Nevada can serve as useful models. PMPs can reduce doctor shopping and diversion from good medical practices by giving physicians a way to identify patients who are receiving controlled substances from other doctors. Purdue supports the adoption by all states of Prescription Monitoring Programs meeting appropriate standards. Purdue encourages Congress to develop legislation to provide states with incentives to adopt such PMPs. Purdue is eager to work with Congress to develop and support such legislation. In addition, Purdue is prepared to utilize its resources to explain the benefits of such a system to physicians and to gain support for such legislation from the medical community. Attached is a copy of Purdue's policy paper on PMPs that sets forth what we believe to be the attributes of a successful program. Purdue is willing to devote promotional resources to introduce such programs to physicians.

Ultimately, solving the problem of prescription drug abuse requires the cooperation of many elements in our community: law enforcement, the schools, religious institutions, parents and family, the courts, the medical community, the press, federal and state legislators, government agencies, social services providers, and the pharmaceutical industry. Purdue is trying to help through our specific programs and our cooperation with the other elements in the community. As noted, PMPs would help. Tamper resistant prescriptions can reduce copying or alteration. Education of responsible doctors and pharmacists can arm them with the tools they need to stop diversion from their practices. A better information system can allow us to know where abuse and diversion is cropping up and allow timely medical education and law enforcement to act earlier to nip these problems in the bud. Development of abuse resistant products can reduce the incidence of abuse. What is needed is cooperation and common purpose. This is a long-standing societal problem that requires a reasoned solution. We are committed to partnering with all involved.

#### 11. Conclusion.

The management of pain is a critical priority of healthcare in this country. Chronic pain affects as many as 50 million Americans and costs the country \$100 billion annually. OxyContin has proven itself an effective weapon in the fight against pain, returning many patients to their families, to their work, and to their enjoyment of life. That advance should not be stunted or reversed because of the illegal activities of those who divert and abuse the drug. We cannot turn back the clock. The answer to these problems is increased education, information and enforcement, not restrictions that will deny patients effective treatment of their pain.

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Federal Document Clearing House Congressional Testimony

December 11, 2001, Tuesday

SECTION: CAPITOL HILL HEARING TESTIMONY

LENGTH: 3144 words

COMMITTEE: HOUSE APPROPRIATIONS

HEADLINE: DANGERS OF OXYCONTIN

TESTIMONY-BY: ASA HUTCHINSON, ADMINISTRATOR

AFFILIATION: DRUG ENFORCEMENT ADMINISTRATION

BODY:

Remarks by

Asa Hutchinson Administrator Drug Enforcement Administration United States Department of Justice

before the House Appropriations Committee: Subcommittee on Commerce, Justice, State and Judiciary regarding Dangers of OxyContin

Executive Summary

Purdue Pharma introduced OxyContin in 1995 as a controlled release formulation of oxycodone, intended for use in the treatment of chronic moderate to severe pain when a continuous, potent, narcotic pain reliever is needed for an extended period. OxyContin contains a large amount of active ingredient compared to other narcotic products. In addition to oral abuse of the intact tablet, crushing the tablet enables abusers to circumvent the controlled release mechanism and to swallow, snort, or inject the drug for a more rapid and intense high. OxyContin has become the number one prescribed Schedule II narcotic in the United States. Increasing abuse of OXYContin has led to an increase of associated criminal activity.

In response to escalating abuse and diversion of the drug, DEA has begun a comprehensive National Action Plan, which concentrates on enforcement and regulatory investigations targeting key points of diversion, including forged and fraudulent prescriptions, pharmacy theft, doctor shoppers, and unscrupulous medical professionals.

The national action plan includes cooperative efforts among DEA, other government agencies and the medical community to send the message that OxyContin is a highly abuseable and addictive substance. Labeling changes have already resulted from these efforts.

e) helping doctors, pharmacists, healthcare providers, law enforcement and the general public become more aware of both the use and abuse of pain medications will enable all of us to make proper and wise decisions regarding the treatment of pain.

Another component of our national action plan is a cooperative effort between DEA and the Food and Drug Administration (FDA) to pursue their jurisdictional authority in a collaborative effort to counter marketing messages that promote OxyContin as less addictive than other opioids. In July 2001, with DEA's support, the FDA and Purdue Pharma reached an agreement regarding labeling changes. The revised package insert for OxyContin contains cautionary language on the drug's abuse and diversion potential. A letter calling attention to the labeling change is being sent by Purdue Pharma to healthcare professionals throughout the country.

Other issues discussed by DEA, FDA, and Purdue Pharma include providing additional information to the medical community on the proper use of OxyContin, as well as the feasibility of reformulating OxyContin in order to reduce its abuse potential. Purdue Pharma recently announced the development of a newly formulated version of OxyContin, and estimates that the new formulation may be marketable in three years.

DEA has initiated meetings with the National Alliance for Model State Drug Laws, which has been the catalyst for the establishment of state Prescription Monitoring Programs to help control prescription drug abuse. Existing data sources such as IMS Health Incorporated™ indicate that the five states with the lowest number of per capita OxyContin prescriptions all have long standing mandated Prescription Monitoring Programs in place (refer to Table 3). The majority of states reporting significant abuse and diversion issues are those without Prescription Monitoring Programs.

Table 3: Rank-Ordered Year 2000 OxyContin Prescriptions B State Per 100,000 Population found on hard copy

#### States with Prescription Monitoring Programs

Although Kentucky has a monitoring program, it has experienced significant problems with the abuse and diversion of OxyContin. Officials in Kentucky reported that responding to doctors requesting checks on patients (in order to ensure they were not attempting to obtain duplicate prescriptions from different doctors) prevented them from initially taking a proactive approach to analyzing the data. Nevertheless, once a problem was noted, the data served as an invaluable tool in determining possible sources. Clearly, data collection alone is not the complete solution. Resources must be dedicated to effective analysis and utilization of the data in order for monitoring to be an effective warning system.

It also is worth noting that individuals from states with monitoring programs often seek out doctors and pharmacies in bordering states to obtain their desired drugs, thereby bypassing their own state's monitoring system. Kentucky OxyContin dealers and users were obtaining supplies from Virginia, West Virginia, Ohio, and other states. Establishing prescription monitoring systems in more states would help resolve this problem.

It is clear that the presence of Prescription Monitoring Programs plays an integral role in addressing the illegal diversion and improper dispensing and acquisition of controlled substances such as OxyContin. Enhancing these data collection systems will provide a better mechanism to gather and evaluate prescription data, which is essential in identifying and responding to newly developing trends and patterns, and most effectively directing our investigative and regulatory resources. In support of this effort, DEA stands ready to work with this Subcommittee to improve and expand data collection efforts on both the State and Federal level. As mentioned above, DEA is also exploring the utilization of new

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FDCH Political Transcripts

December 11, 2001, Tuesday

TYPE: COMMITTEE HEARING

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COMMITTEE: JUSTICE, STATE, JUDICIARY AND RELATED AGENCIES SUBCOMMITTEE

SUBCOMMITTEE: HOUSE APPROPRIATIONS COMMERCE

HEADLINE: U.S. REPRESENTATIVE FRANK WOLF (R-VA) HOLDS HEARING ON  
OXYCONTIN

SPEAKER:

U.S. REPRESENTATIVE FRANK WOLF (R-VA), CHAIRMAN

LOCATION: WASHINGTON, D.C.

WITNESSES:

ASA HUTCHINSON, ADMINISTRATOR, DRUG ENFORCEMENT ADMINISTRATION,  
DEPARTMENT OF JUSTICE

PROSECUTOR TOMMY MCELYEA, LEE COUNTY, VIRGINIA

LIEUTENANT STEVEN HUDSON, NARCOTICS TASK FORCE, PRINCE WILLIAM/MANASSA,  
VIRGINIA

ROD MAGGARD, FORMER POLICE CHIEF, HAZARD, KENTUCKY

CAPTAIN RICH HALL, WEST VIRGINIA STATE POLICE

ROLLY SULLIVAN, PROFESSOR, BEHAVIORAL MEDICINE AND PSYCHIATRY

DONNIE COOTS, HAZARD, KENTUCKY

PAUL GOLDENHEIM, EXECUTIVE VICE PRESIDENT, RESEARCH, DEVELOPMENT &  
REGULATORY & MEDICAL AFFAIRS, PURDUE PHARMA

MARY SIMMONS, FIRST VICE PRESIDENT, AMERICAN CANCER SOCIETY

MICHAEL ASHBURN, PRESIDENT, AMERICAN ACADEMY OF PAIN MEDICINE

PETER STAATS, DIRECTOR, DIVISION OF PAIN MEDICINE, JOHNS HOPKINS

BODY:

HOUSE COMMITTEE ON APPROPRIATIONS: SUBCOMMITTEE ON COMMERCE,  
JUSTICE, STATE AND JUDICIARY HOLDS A HEARING ON OXYCONTIN, A PAIN  
MEDICATION



How we go about doing this and what I hope we can bring a focus on today is working toward a quick, meaningful, and successful solution. One solution might be to require that all states institute prescription monitoring programs. I understand that 18 states have prescription monitoring programs now. We'll be interested in hearing more from the panelists about the benefit of those and perhaps even a nationwide system.

I'm pleased to report that the fiscal year 2002 appropriations act for the Departments of Commerce, Justice, State, and Judiciary includes \$2 million for the Department of Justice to fund grants to help states that don't have prescription drug monitoring programs to establish them. We're also looking forward to hearing from the state and local law enforcement representatives about their day to day experiences with OxyContin and its devastating effect on their communities.

In that same vein, we'll be hearing from the father of a recovering OxyContin addict. We're also looking forward to hearing from Dr. Sullivan, who has extensive experience in treating drug addicts.

I also want to thank the representatives from Purdue Pharma for appearing today. You have developed a drug that has brought relief to many. Regrettably, it has also brought with it many problems in the essence of hurting communities and destroying some families. We look forward to your testimony.

Finally, we will hear from pain management experts and other medical professionals about the importance of OxyContin in their efforts to treat patients suffering from severe pain and assure that people who need access to these powerful medications can retain that access. We will also be hearing from representatives from the American Cancer Society and the American Academy of Pain Medicine and the Johns Hopkins University.

Before we hear from our first witness, the head of DEA, our former colleague, Mr. Hutchinson, we'll first have opening statements from Mr. Serrano and then Mr. Rogers.

SERRANO: Thank you, Mr. Chairman. I will be very brief. Let me first thank you for putting together this hearing. I know how important this issue is to you and, indeed, how important it is to all of us.

As you know, Mr. Chairman and my colleagues, I represent a district in the South Bronx, and so the issue of drug abuse is one that I'm very familiar with in terms of the pain that it has caused all my constituents. For such a long time, my district was one of the districts with the most crime in the nation, and yet that crime was very much related, mostly related, to the issue of drug abuse.

So today, I sit here with you, wanting to be helpful in every way I can to deal with this issue which is not one yet seen in the inner cities, but that I'm sure will be seen in a short time. However, I could not pass up the opportunity to deal with, I think, the greater issue at hand, and that is that our great nation has, in my opinion, in the past not paid attention to the issue of drug abuse the way it should, perhaps because, at times, drug abuse was seen as an inner city problem. We spent too much time blaming those people for their condition and just tied it as part of other problems that existed in the society rather than deal with it for what it was, a serious problem.

And so if you look at our budgets, one could argue that we haven't spent enough money on preventive medicine in this area and certainly have not spent enough money and resources on treatment centers. I've known too many people, just too many people, who have wasted their lives away and their youth away, people I grew up with, with different kinds of drugs, the last one being crack cocaine.